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10/572,644

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Thomas Thisted

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EXAMINER

LUNDGREN, JEFFREY S

ART UNIT

PAPER NUMBER

1639

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,644	Applicant(s) THISTED ET AL.	
	Examiner JEFFREY S. LUNDGREN	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 69-82 is/are pending in the application.
- 4a) Of the above claim(s) 69-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/8/08; 7/29/09; 9/15/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Newly submitted claims 69-82 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicants have now presented claims to multiple methods and therefore are considered secondary to the first invention of the originally presented claims under 37 C.F.R. § 1.475(d).

Moreover, the withdrawn claims appear to have been filed in U.S. Application No. 12/095,778, which further supports the understanding that claims 69-82 are directed to alternative inventions than those of claims 1-20.

37 C.F.R. § 1.475 – *Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.*

- (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (“requirement of unity of invention”). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
- (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
 - (1) A product and a process specially adapted for the manufacture of said product; or
 - (2) A product and process of use of said product; or
 - (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
 - (4) A process and an apparatus or means specifically designed for carrying out the said process; or
 - (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
- (c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
- (d) **If multiple products, processes of manufacture or uses are claimed,** the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).
- (e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, claims 69-82 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-20 are the subject of the Office Action below.

Objection to the Specification under 37 C.F.R. § 1.77(b)(8).

The specification is objected under 37 C.F.R. § 1.77(b)(8) for not providing a complete Brief Description of the Figures. Correction without the addition of new matter is required.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on May 8, 2008, July 29, 2009, and September 15, 2009, have been considered by the Examiner. The submissions are in compliance with the provisions of 37 CFR § 1.97. Enclosed with this Office Action is a return of each copy of the Form PTO-1449 with the Examiner's initials and signature indicating those references that have been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for reciting the phrase "coupling to the target oligonucleotide(s) the identifier oligonucleotide of complexes comprising display molecules binding to the target" because one of ordinary skill in the art could not reasonably determine the metes and bounds of this limitation. Specifically, the phrase is grammatically awkward and does not convey with reasonable clarity the relationships between the claim elements. Correction is required.

Claim 4 is indefinite for reciting the phrase "the chemical entities" because there is insufficient antecedent basis in the claim (*i.e.*, which particular chemical entities?).

Claim 11 is indefinite for reciting the phrase "the nascent display molecule" because there is insufficient antecedent basis in the claim.

Claim 12 is indefinite for reciting the phrase "the information" because there is insufficient antecedent basis in the claim.

Claim 13 is indefinite for reciting the phrase "the chemical entities" because there is insufficient antecedent basis in the claim.

Claim 14 is indefinite for reciting the phrase "the codons" because there is insufficient antecedent basis in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 are obvious over Szostak and Rabani:

Claims 1-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Szostak *et al.*, U.S. Patent No. 6,207,446, in view of Rabani *et al.*, U.S. Patent Appl. Publication No. 2004/0161741, published on August 19, 2004.

The claimed invention is generally directed towards a binding assay, wherein a target compound and a library of putative binders having a display molecule (*i.e.*, bifunctional complex) are reacted. Each of the target(s) and display molecules each have an associated oligonucleotide; the oligonucleotide of the putative binder “codes” for the display molecule (*i.e.*, not necessarily as a codon in the sense of biological translation on a ribosome, or naturally occurring codon).

Specifically, claim 1 is directed to a method for identifying display molecule(s) having affinity towards molecular target(s), comprising the steps of

mixing one or more molecular target(s) associated with target oligonucleotide(s) and a library of bifunctional complexes, each bifunctional complex of the library comprising a display molecule attached to an identifier oligonucleotide, which codes for said display molecule,

coupling to the target oligonucleotide(s) the identifier oligonucleotide of complexes comprising display molecules binding to the target, and

deducing the identity of the binding display molecule(s) and/or the molecular target(s) from the coupled product between the identifier oligonucleotide(s) and the target oligonucleotide(s).

Szostak teaches a general method for the selection of proteins with desired functions using fusions in which these proteins are covalently linked to their own messenger RNAs. These RNA-protein fusions are synthesized by in vitro or in situ translation of mRNA pools containing a peptide acceptor attached to their 3' ends (FIG. 1B). In one preferred embodiment, after readthrough of the open reading frame of the message, the ribosome pauses when it reaches the designed pause site, and the acceptor moiety occupies the ribosomal A site and accepts the

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nascent peptide chain from the peptidyl-tRNA in the P site to generate the RNA-protein fusion (FIG. 1C). The covalent link between the protein and the RNA (in the form of an amide bond between the 3' end of the mRNA and the C-terminus of the protein which it encodes) allows the genetic information in the protein to be recovered and amplified (e.g., by PCR) following selection by reverse transcription of the RNA. Once the fusion is generated, selection or enrichment is carried out based on the properties of the mRNA-protein fusion, or, alternatively, reverse transcription may be carried out using the mRNA template while it is attached to the protein to avoid any effect of the single-stranded RNA on the selection. When the mRNA-protein construct is used, selected fusions may be tested to determine which moiety (the protein, the RNA, or both) provides the desired function (See Figures 1A-C, Figure 2, and descriptions thereof).

Although Szostak teaches the selection of proteins having a fused nucleic acid that codes for the protein, wherein the protein binds to a target, Szostak does not explicitly teach that the target be fused to a nucleic acid.

Rabani teaches invention provides novel compositions and processes for analyte detection, quantification and amplification. Nucleic acid arrays and libraries of analytes are usefully incorporated into such compositions and processes. Universal detection elements, signaling entities and the like are employed to detect and if necessary or desirable, to quantify analytes. Amplification of target analytes are also provided by the compositions and processes that are taught by Rabani. In particular, Rabani teaches a method that utilizes a nucleic acid-peptide hybrid immobilized to a substrate, wherein the binding between the peptide and a putative target is analyzed (see Figure 26 and description thereof).

One of ordinary skill in the art would have had a reasonable expectation of success in arriving at the invention as claimed because each of Szostak and Rabani are directed to screening putative ligand-target binding pairs wherein at least one of the binding components is a nascent peptide-oligonucleotide complex. One of ordinary skill in the art would have been motivated to utilize the approach of Rabani with that of Szostak because of the advantages of being able to identify both the target and the library member via their respective attached nucleic acid. Therefore, the invention was *prima facie* obvious at the time it was invented.

Common Ownership of Claimed Invention Presumed

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. §§ 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Conclusions

No claim is allowable.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey S. Lundgren/

Primary Examiner, Art Unit 1639